

EXHIBIT A

THE COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, ss.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION NO. 12-2322

DALE HOWARD, as Personal Representative of
the Estate of KIMBERLY NOVAK HOWARD,
Decedent, and DALE HOWARD, Individually,

Plaintiffs,

v.

GENENTECH, INC., GENENTECH USA, INC.,
and BIOGEN IDEC, INC.,

Defendants.

FILED
IN THE OFFICE OF THE
CLERK OF COURTS
FOR THE COUNTY OF MIDDLESEX
JUN 22 2012

CLERK

9366A000006/22/12CIVIL	240.00
9366A000006/22/12CIVIL	240.00
9366A000006/22/12SURCHARGE	15.00
9366A000006/22/12FEES	20.00

COMPLAINT AND DEMAND FOR JURY TRIAL

PARTIES

1. Plaintiff, Dale Howard, is an individual residing in Andover, Minnesota (Anoka County) and is the Personal Representative of the Estate of his late wife, Kimberly Novak Howard. Plaintiff's appointment was pursuant to an Notice of Informal Appointment of Personal Representative and Notice to Creditors entered by the Registrar of the District Court for the Tenth Judicial District, Probate Division, for the County of Anoka, State of Minnesota, dated July 21, 2011.

2. Plaintiff brings this action as the Personal Representative of the Estate of Kimberly Novak Howard and in his individual capacity for damages arising out of Kimberly Novak Howard's pain and suffering prior to her death and Kimberly Novak Howard's wrongful death.

3. Plaintiff, as Personal Representative, makes all viable legal claims in this action pursuant to M.G.L. c. 229 § 2, *et seq.*, for the products liability-related injury and wrongful death of Kimberly Novak Howard on August 23, 2010.

4. Kimberly Novak Howard died on August 23, 2010 at age 47. Mrs. Novak Howard was a resident of Andover, Minnesota, at the time of her death, and is survived by her husband, plaintiff Dale Howard, the Personal Representative of her Estate.

5. This is a wrongful death action pursuant to the provisions of M.G.L. c. 229, § 2, by plaintiff, as Personal Representative of the Estate of Kimberly Novak Howard, deceased, and by plaintiff individually for loss of consortium.

6. Defendant Genentech, Inc. ("Genentech") is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business in the City of South San Francisco, California.

7. Defendant Genentech USA, Inc. ("Genentech USA") is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business in the San Francisco, California. At all times, Genentech USA has been a wholly-owned subsidiary of Genentech.

8. Defendant Biogen IDEC, Inc. ("Biogen") is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at 14 Cambridge Center, Cambridge, Commonwealth of Massachusetts (Middlesex County).

9. At all times relevant hereto, Biogen was a partner of Genentech USA in connection with the marketing, sales, distribution, research, testing and development of a pharmaceutical drug product commercially know as Rituxan, generically known as rituximab.

10. Genentech regularly conducts and/or solicits substantial business in the Commonwealth of Massachusetts, and/or engages in a persistent course of conduct in the Commonwealth of Massachusetts, and/or derives substantial revenue from goods sold and used in the Commonwealth of Massachusetts.

11. Plaintiff's causes of action arise, in part, from Genentech's (i) transaction of business in the Commonwealth of Massachusetts, (ii) contracting to supply goods and/or services

in the Commonwealth of Massachusetts, (iii) causing tortious injury by an act or omission in the Commonwealth of Massachusetts, (iv) causing tortious injury in the Commonwealth of Massachusetts by an act or omission outside of the Commonwealth of Massachusetts.

12. Biogen describes itself as “a global leader in the development, manufacturing, and commercialization of novel therapies.”

13. At all times relevant hereto, Genentech, in collaboration and/or in joint enterprise with Biogen, designed, developed, researched, manufactured, tested, packaged, promoted, marketed, sold and/or distributed Rituxan, a pharmaceutical drug product for the treatment of rheumatoid arthritis, non-Hodgkins lymphoma chronic lymphatic leukemia (“CLL”), and other human diseases.

14. Rituxan (rituximab) is a potent immunosuppressant monoclonal antibody drug.

15. At all times relevant hereto, Genentech designed, developed, researched, manufactured, tested, packaged, promoted, marketed, sold and distributed Rituxan.

16. At all times relevant hereto, Genentech, in collaboration and in joint enterprise with Biogen, designed, developed and implemented, within the Commonwealth of Massachusetts, the protocols for animal studies of Rituxan.

17. At all times relevant hereto, Genentech, in collaboration and in joint enterprise with Biogen, designed, developed and implemented, within the Commonwealth of Massachusetts, the protocols for laboratory testing of Rituxan.

18. The input, feedback, acts and omissions of Biogen, as alleged herein, had a significant impact within the Commonwealth of Massachusetts.

19. The input, feedback, acts and omissions of Biogen, as alleged herein, had a significant impact on the course of conduct that Genentech followed and the actions taken by Genentech with respect to Rituxan within the Commonwealth of Massachusetts.

20. At all times relevant hereto, Genentech, in collaboration and in joint enterprise with Biogen, reviewed, evaluated and monitored, within the Commonwealth of Massachusetts, animal studies that included Rituxan.

21. At all times relevant hereto, Genentech, in collaboration and in joint enterprise with Biogen, reviewed, evaluated and monitored, within the Commonwealth of Massachusetts, laboratory studies that included Rituxan.

FACTS COMMON TO ALL COUNTS

22. Kimberly Novak Howard was born on July 23, 1963.

23. Rituxan was prescribed for and ingested by Kimberly Novak Howard, from June 2007 to November 2007, and from February 2009 to February 2010.

24. After, and as a proximate result of taking Rituxan, Kimberly Novak Howard developed an opportunistic infection known as Progressive Multifocal Leukoencephalopathy ("PML").

25. PML is a typically fatal brain disease caused by the immunosuppressive effects of Rituxan and other immunosuppressant drugs.

26. As further alleged below, as a result of taking Rituxan and contracting PML, Kimberly Novak Howard endured severe pain and suffering and died.

27. As further alleged below, Kimberly Novak Howard's death was a direct and proximate result of the negligence, gross negligence, recklessness, carelessness, breaches of warranty, fraud, unfair and deceptive practices and other wrongful conduct on the part of the defendants.

28. PML is an almost-always fatal disease of the nervous system caused by a polyomavirus (the "JC Virus") that typically only strikes people with severely impaired immune systems. PML causes symptoms such as impaired cognition, cortical blindness and weakness on one side of the body, and almost always results in death.

29. The JC Virus, which causes PML, is latent and asymptomatic in the kidneys of most adults following infection in adolescence and only invades the brain when the immune system is severely impaired, which allows the virus to replicate uncontrollably.

30. The symptoms of PML are the result of an infection that causes the loss of white matter (which is made up of myelin, a substance that surrounds and protects nerve fibers) in multiple areas of the brain. Without the protection of myelin, nerve signals cannot travel successfully from the brain to the rest of the body.

31. The most prominent early symptoms of PML are clumsiness; progressive weakness; and visual, speech, and sometimes, personality changes. The progression of symptoms leads to disability and death.

32. Rituxan has been associated with PML and with fatal infusion reactions, tumor lysis syndrome, severe mucocutaneous reactions, cardiovascular injuries, and other opportunistic infections, including: pneumocystis jirovecii pneumonia, Epstein-Barr-virus ("EBV") - associated hepatitis, generalized herpes zoster, BALT-lymphoma, and herpes encephalitis.

33. In 1995, Genentech and IDEC Pharmaceuticals Corporation ("IDEC") signed an agreement to develop and commercialize Rituxan.

34. In November 1997, the FDA approved Rituxan for the treatment of cancer.

35. In 2001, the FDA approved a supplemental Biological License Application for Rituxan adding several new uses, including: the retreatment of patients with Rituxan who have relapsed following initial Rituxan therapy, the use of eight weekly doses of Rituxan per course of treatment, and the treatment with Rituxan of patients with bulky disease (lesions > 10cm).

36. In 2003, Biogen and IDEC merged to form Biogen Idec Inc.

37. In 2006, the FDA approved Rituxan for the treatment of patients with diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin; vincristine and prednisone) or other anthracycline-based

chemotherapy regimens; in combination with methotrexate in adult patients with rheumatoid arthritis; and for the treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma ("NHL") as a single agent.

38. Biogen manufactures a second monoclonal antibody by the name of Tysabri. In November 2004, Biogen received FDA approval to market Tysabri. Tysabri, like Rituxan, is an immunosuppressant drug. The FDA approved Tysabri for use in patients with multiple sclerosis.

39. On February 28, 2005, Biogen withdrew Tysabri from the market pending an investigation of the deaths of at least two patients who had taken Tysabri and had subsequently been diagnosed with PML.

40. While, on June 5, 2006, Tysabri returned to the market, the FDA forced Biogen to include many warnings, including black box warnings, and extremely stringent patient consent forms, concerning the significant risk of serious opportunistic infections, including PML, in Tysabri's label.

41. Biogen, as a result of its manufacturing and marketing of both Tysabri and Rituxan, two monoclonal antibodies, knew, or recklessly disregarded the significant risk that Rituxan's severe immunosuppressive effect could result in severe opportunistic infections, including PML.

42. Biogen, as a result of its manufacturing and marketing of both Tysabri and Rituxan, two monoclonal antibodies, knew or should have known that Rituxan virtually "turns off" the immune system and ultimately can lead to a patient contracting PML.

43. As a proximate result of the defective medication, to wit, Rituxan, manufactured and marketed by Genentech and Biogen, Kimberly Novak Howard suffered and died on August 23, 2010.

44. In June of 2007, Kimberly Novak Howard was diagnosed as having non-Hodgkin's lymphoma.

45. Between June of 2007 and November of 2007 Kimberly Novak Howard was treated with eight cycles of Rituxan.

46. In February of 2009, Kimberly Novak Howard was started on four cycles of Rituxan and received maintenance Rituxan once every 12 weeks from May of 2009 to February of 2010.

47. At no time was either Kimberly Novak Howard or plaintiff informed or warned by defendants, or by any of them, or by any of their agents, servants or employees, of Rituxan's immunosuppressive qualities.

48. At no time was either Kimberly Novak Howard or plaintiff informed or warned by defendants, or by any of them, or by any of their agents, servants or employees, that Kimberly Novak Howard's use of Rituxan created a significant risk of Mrs. Howard developing opportunistic infections such as PML.

49. At no time was either Kimberly Novak Howard or plaintiff informed or warned by defendants, or by any of them, or by any of their agents, servants or employees, that Rituxan could cause the development of fatal infections such as PML.

50. At no time was either Kimberly Novak Howard or plaintiff informed or warned by defendants, or by any of them, or by any of their agents, servants or employees, that Kimberly Novak Howard's use of Rituxan could cause her death.

51. The aforesaid risks of Rituxan were or, at the very least, should have been known to defendants and to each of them.

52. Following her use of Rituxan, Kimberly Novak Howard's health began to deteriorate, and she lost the ability to focus, her memory, her left sided strength, and her ability to avoid objects while walking and suffered visual, speech, and personality changes.

53. After MRIs of her brain, a spinal tap of her spinal fluid, and biopsies of her, Kimberly Novak Howard was diagnosed as having PML.

54. After enduring intractable pain and suffering, Kimberly Novak Howard died as a result of PML on August 23, 2010. Kimberly Novak Howard's death certificate lists PML as the cause of her death.

55. As a direct and proximate result of defendants' negligence, gross negligence, carelessness, recklessness, breaches of warranty, and other wrongful conduct, Kimberly Novak Howard endured unrelenting pain and suffering prior to her death.

56. Plaintiff suffered and continues to suffer emotional distress, grief, loss of care, and loss of assistance, society, companionship, comfort and guidance, and all other matters cognizable under M.G.L. c. 229, § 2, *et seq.*

COUNT I

Wrongful Death G.L. c.229, § 2
Negligence

57. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 56 of this Complaint as if set forth herein at length.

58. Defendants were at all relevant times engaged in the design, development, research, manufacture, testing, packaging, promotion, marketing, sale and distribution of pharmaceutical products, including Rituxan.

59. The death of Kimberly Novak Howard and the additional injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of defendants:

a. In their design, development, research, manufacture, testing, packaging, promotion, marketing, sale and distribution of Rituxan;

b. In their failure to warn or instruct, or adequately warn or adequately instruct, users of Rituxan, including Kimberly Novak Howard, of Rituxan's dangerous and defective characteristics;

c. By dispensing and distributing Rituxan and placing it in the channels of trade and commerce when defendants knew, or with reasonable care should have known, Rituxan to be dangerous and defective, and placing Rituxan in the channels of trade and commerce when, in the exercise of reasonable care, defendants ought to have foreseen that Rituxan would come into contact with persons such as Kimberly Novak Howard who were ignorant of its dangerous and defective nature and condition, and in failing to use reasonable care to prevent injury to such persons, including Kimberly Novak Howard;

d. In their failure to test or sufficiently test the immunosuppressive qualities of Rituxan and their ramifications;

e. In their failure to warn or instruct, or adequately warn or adequately instruct, users of Rituxan, including Kimberly Novak Howard, of Rituxan's immunosuppressive qualities;

f. In their failure to warn or instruct, or adequately warn or adequately instruct, users of Rituxan, including Kimberly Novak Howard, that Rituxan created a significant risk of developing opportunistic infections such as PML;

g. In failing to warn prescribing physicians or consumer patients of the actual and known risk of contracting PML inherent in the use of Rituxan;

h. In failing to warn prescribing physicians or consumer patients of the early symptoms of PML, and of the risk of contracting opportunistic infections such as PML, which was, or should have been, known to defendants prior to Kimberly Novak Howard's use of Rituxan;

i. In their promotion of the use of Rituxan in an overly aggressive, deceitful and fraudulent manner, despite evidence of its defective and dangerous characteristics due to its propensity to cause opportunistic infections such as PML, and without first

having conducted sufficient pre-clinical studies and tests to ensure that Rituxan was safe for use by humans.

60. Defendants had a duty to warn prescribing physicians and consumers of Rituxan of the known or suspected risks arising from use of Rituxan and to conduct further pre-clinical studies and tests to determine the safety of Rituxan.

61. As a direct and proximate result of the negligence of defendants, their agents, servants and employees, Kimberly Novak Howard was caused to endure intractable pain of suffering and was caused to die, and her estate, and plaintiff have been seriously damaged as a result thereof in an amount to be proven at trial.

WHEREFORE, plaintiff, as Personal Representative of the Estate of Kimberly Novak Howard, demands judgment against defendants, and each of them, together with costs and interest.

COUNT II

Wrongful Death G.L. c.229, § 2 Punitive Damages

62. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 56 and 58 through 61 of this Complaint as if set forth herein at length.

63. Defendants' aforesaid acts and omissions constituted malicious, willful, wanton, grossly negligent and reckless conduct within the meaning of G.L. c. 229, § 2.

64. By reason of the foregoing plaintiff, as Personal Representative of the Estate of Kimberly Novak Howard, is entitled to recover punitive and exemplary damages in an amount to be proven at trial.

WHEREFORE, plaintiff, as Personal Representative of the Estate of Kimberly Novak Howard, demands judgment against defendants, and each of them, together with costs and interest.

COUNT III

Wrongful Death G.L. c.229, § 6
Conscious Pain and Suffering

65. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 56, 58 through 61, and 63 through 64 of this Complaint as if set forth herein at length.

66. As a consequence of the events alleged in this Complaint, and as a direct and proximate result of the negligence of defendants, Kimberly Novak Howard was caused considerable pain and suffering prior to her death, which injuries to her are compensable under G.L. c. 229, § 6.

67. By reason of the foregoing, plaintiff, as Personal Representative of the Estate of Kimberly Novak Howard, is entitled to recover damages for the pain and suffering defendants caused to Kimberly Novak Howard in an amount to be proven at trial.

WHEREFORE, plaintiff, as Personal Representative of the Estate of Kimberly Novak Howard, demands judgment against defendants, and each of them, together with costs and interest.

COUNT IV

Breach of Warranties

68. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 56, 58 through 61, 63 through 64, and 66 through 67 of this Complaint as if set forth herein at length.

69. Defendants expressly and impliedly warranted to the public and to Kimberly Novak Howard that Rituxan was reasonably safe, merchantable, and fit for its intended purposes and uses.

70. Rituxan was designed, developed, manufactured and distributed by defendants, and was expected by them to reach and did reach Kimberly Novak Howard without a substantial change in its condition.

71. Defendants, their agents, servants and employees, breached defendants' warranties because Rituxan was unsafe, was not of merchantable quality, was unfit for its intended uses and purposes, and had unreasonably dangerous immunosuppressive characteristics which caused its users to develop opportunistic infections such as PML.

72. Defendants, their agents, servants and employees, also failed to provide adequate warnings and instructions with Rituxan, which rendered Rituxan unreasonably dangerous and unfit for the ordinary purposes for which it is used, in breach of defendants' warranties.

73. As a direct and proximate result of defendants' breaches of warranty, Kimberly Novak Howard was caused to endure intractable pain and suffering and was caused to die, and her estate is entitled to recover the damages suffered by Kimberly Novak Howard in an amount to be proven at trial.

WHEREFORE, plaintiff, as Personal Representative of the Estate of Kimberly Novak Howard, demands judgment against defendants, and each of them, together with costs and interest.

COUNT V

Fraud

74. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 56, 58 through 61, 63 through 64, 66 through 67, and 69 through 73 of this Complaint as if set forth herein at length.

75. At no time did defendants, or any of them, disclose to or inform Kimberly Novak Howard or plaintiff that animal, human and laboratory studies of Rituxan showed significant

risks of adverse effects resulting from suppression of the immune system despite the fact that defendants had knowledge that such life threatening side effects were possible.

76. At no time did defendants, or any of them, disclose to or inform Kimberly Novak Howard or plaintiff that the adverse side effects of Rituxan were cumulative such that there was a significant possibility that they would not become apparent for a number of years after Kimberly Novak Howard commenced Rituxan use.

77. At no time did defendants, of any of them, disclose to or inform Kimberly Novak Howard or plaintiff that professional journals, articles and papers questioned the use and safety of Rituxan in humans, or that such journals, articles and papers were in their possession.

78. At all relevant times, defendants represented to Kimberly Novak Howard and to plaintiff that Rituxan was reasonably safe and effective.

79. Defendants' acts, omissions and representations, as alleged in this complaint, constituted false statements of material fact made to induce Kimberly Novak Howard to take Rituxan.

80. Kimberly Novak Howard reasonably relied upon defendants' acts, omissions and representations to her detriment, as a result of which Kimberly Novak Howard endured intractable pain and suffering and was caused to die, and her estate is entitled to recover the damages suffered by Kimberly Novak Howard in an amount to be proven at trial.

WHEREFORE, plaintiff, as Personal Representative of the Estate of Kimberly Novak Howard, demands judgment against defendants, and each of them, together with costs and interest.

COUNT VI

Loss of Consortium

81. Plaintiff, individually, repeats and realleges each and every allegation contained in paragraphs 1 through 56, 58 through 61, 63 through 64, 66 through 67, 69 through 73, and 75 through 80 of this Complaint as if set forth herein at length.

82. Plaintiff was the Husband of Kimberly Novak Howard.

83. As a direct and proximate result of defendants' negligence, plaintiff has lost and been deprived of the love, companionship, comfort, care, services and support of his wife, Kimberly Novak Howard, and has been damaged in an amount to be proven at trial.

WHEREFORE, plaintiff, individually, demands judgment against defendants, together with interest and costs.

PRAYER FOR RELIEF

Plaintiff, as Personal Representative of the Estate of Kimberly Novak Howard, demands judgment in an amount to be proven at trial to compensate for the damages defendants and each of them caused to Kimberly Novak Howard as alleged in Counts I, III, IV, and V, together with punitive damages in an amount to be proven at trial as alleged in Count II, together with interest, costs and reasonable attorneys' fees.

Plaintiff, individually, demands judgment in an amount to be proven at trial for his loss of consortium as a result of the death of his wife, Kimberly Novak Howard, together with interest, costs and reasonable attorneys' fees.

Plaintiff, as Personal Representative of the Estate of Kimberly Novak Howard and Individually demands judgment of such other, further or different relief as may be just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, as Personal Representative of the Estate of Kimberly Novak Howard and
Individually, hereby demands a trial by Jury.

DATED: June 21, 2012

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